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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,584	12/21/2001	Craig A. Rosen	PF112P1D2	4809

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,584	ROSEN ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *20,21,51,67,68 and 90-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-19,22-50,52-66,69-89 and 97-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12/21/01 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Comparison*.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 4/26/04 has been entered into the record. Claims 1-110 are pending in this application. Claims 1-19, 22-50, 52-66, 69-89 and 97-110 are the subject of this Office Action. See the response to the traversal below.

B. The Information Disclosure Statement dated 4/26/04 has been entered into the record. All references have been considered.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Response to Traversal

A. Applicants' discussion with Gary Kunz regarding rejoining Groups I and III is noted. The Examiner brings to Applicants' attention that, unlike protein claims, which, in this format, would be less of a burden to search, antibody claims are a more serious burden. Antibodies which bind one fragment of the claimed protein would not necessarily, nor be expected to, bind other fragments of the same protein. Therefore, a search for antibodies to one fragment would not overlap the search for antibodies to another fragment. Therefore, these antibodies are distinct and should entail separate searches for separate inventions. However, since Applicants telephoned the Examiner's supervisor, Groups I and III will be combined and the Groups drawn to methods commensurate in scope to the claimed invention will be rejoined if they raise no new issues under 35 USC 112.

3. Specification

A. All objections to the specification have been withdrawn in view of Applicants' amendments.

4. Claim Objections

A. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 33 recites identical limitations to claim 31, which includes the limitations of claim 22 and adds the limitation "monoclonal."

B. The syntax of claims 52, 69, 76 and 97 can be improved by amending part (b) to recite "in a host cell."

C. Claim 53, 55 and 56 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims recite identical limitations to either claims 2-4 (depending on what is defined as the 'full-length,' as well as 8 and 9, since the DNA encoding ATCC 97149 encodes the protein defined in claim 1, as well as its dependent claims.

D. Claim 70, 72 and 73 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims recite identical limitations to either claims 23-25 (depending on what is defined as the 'full-length,' as well as 29 and 30, since the DNA encoding ATCC 97149 encodes the protein defined in claim 22, as well as its dependent claims.

E. Claim 76 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 76 recites identical limitations to claims 74 and 33, which includes the limitations of claims 69 and adds the limitation "monoclonal."

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of 52-66, 69-89 and 97-110 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' submission of a statement of Biological Deposit over the attorney's signature.

B. The rejection of claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and the Declaration by Dr. Roschke regarding the phrase "specifically binds."

C. The rejection of claims 52, 54. 58-66, 69, 71, 74-76, 78, 82-89 and 97 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to delete the term "mature."

D. The rejection of claims 98, 100, 106 and 108 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to delete the term "pharmaceutically acceptable."

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 52, 54, 58-66, 69, 71, 74-76, 78, 82-89 and 97 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to delete the term "mature."

7. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66 and 69-89 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' arguments and the Declaration by Dr. Roschke regarding the phrase "specifically binds."

B. Claims 18, 19, 49, 50, 65, 66, 88, 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how a cell can produce a fragment of an antibody, which may comprise as few as one amino acid. It appears that the only way to have a cell produce a fragment of a protein is via recombinant DNA techniques, which do not appear to be the subject of this invention.

8. Double Patenting

A. Claims 1-5, 8-10, 22-26, 29-37, 40-42, 52-66, 69-89 and 97-110 remain provisionally rejected under 35 U.S.C. 101 for the reasons already of record on page 7 of the Office Action dated 11/26/03. Claim 19 of 09/499,468 has been canceled and Applicants stated that they will consider filing a Terminal Disclaimer in the present application over the any of claims 20, 21 or 21 of the co-pending applications.

9. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-5, 10, 22-26, 31-37, 42, 52-54, 57, 63-66, 69-71, 74-78, 81, 83, 86-89 and 97-100, 103-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Houck et al. The claims recite an isolated antibody that specifically binds to the protein of SEQ ID NO:2. Houck et al. teach a protein which has a 7 consecutive amino acid overlap with the protein of the present invention (Sequence Comparison A). Houck also teach the use of a monoclonal antibody to VEGF to immunoprecipitate the protein (page 1809). The reference is silent with respect to how the antibody was produced. However, the artisan would immediately envision inoculating an animal with a VEGF protein to produce the antibody of interest. The reference is also silent with respect to whether or not the antibody binds the protein in a Western Blot, or ELISA as well as with respect to the cells and hybridomas that produce the antibodies. Therefore, in absence of evidence to the contrary, it would be expected that these antibodies would bind the protein in these assays. The artisan would also immediately envision the use of an isolated cell or hybridoma to produce the antibody. The artisan would also immediately envision the antibody in a pharmaceutical carrier such as buffer or water.

10. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-5, 10, 22-26, 31-37, 42, 52-54, 57-66, 69-71, 74-78, 81-89 and 97-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houck et al. in view of Colwell et al. The teachings of Houck are recited above. Houck do not specifically teach the use of hybridomas, or antibodies from animals. However, Colwell do teach these limitations including methods of culturing cells (last paragraph of page 42 and pages 43-46). Compositions comprising pharmaceutically acceptable carriers are also

taught ("Media and Reagents" on page 48). The use of antibodies in ELISAs is also taught ("Assay Methods" on page 48). It would have been obvious to the artisan to have used the methods of Colwell to produce the antibody to the protein of Houck since methods of producing both monoclonal and polyclonal antibodies were well-known at the time of the present invention and the production of monoclonals allows for a more antigen-specific antibody, which would be beneficial for use in treatment.

Neither reference teaches labeling the antibody, or a glycosylated antibody. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have labeled the antibody to use in assays, such as for protein localization and expression studies (e.g. immunoassays and immunohistochemical staining). Glycosylation is a natural process when antibodies are produced in animals and may contribute to function or half-life. Furthermore, it is well-known in the art that chimeric, single-chain and Fab-fragment antibodies can have a major effect on immunogenicity, effector function and half-life. Furthermore, antibody fragments retain specificity and have increased the penetrability of solid tumors (single-chain variable fragments).

12. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 09, 2004

ROBERT LANDSMAN
PATENT EXAMINER